Message

**From:** Zerfas, William [Zerfas.William@epa.gov]
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**To:** OPP HED [OPP_HED@epa.gov]
**Subject:** HED Weeklies for the weeks ending 11/13/20
**Attachments:** HED Weekly 11-13-20 final.docx

# HED NEWS

**Week Ending**
**11/13/20**
**Bill Zerfas, Editor**

For the Office Director

**** SENSITIVE – NOT FOR DISTRIBUTION ****

# Ex. 5 Deliberative Process (DP)

**Pre-Submission Meeting with the Registrant for 2,4-DP.** On Tuesday November 10th, members of HED, EFED, and RD met with representatives of Nufarm to discuss the potential submission plans for 2,4-DP. Proposed new uses of 2,4-DP include first food uses for this chemical on barley, wheat, corn (field, sweet), sorghum, soybean, citrus (import tolerance). Among the discussion points were the confined rotational crop studies and plant metabolism studies. (David Nadrchal, 703-347-0365)

**Meeting with Propargite Registrants.** On November 10th, HED's RAB V/VII propargite team, along with staff from PRD, BEAD, and EFED, met with representatives from Extremis, Aceto Life Sciences, and MacDermid Ag Solutions as a follow up to a November 3rd meeting to discuss risk mitigation proposed to address issues identified in the propargite draft human health risk assessment (DRA) for registration review. The recent discussion included confirming a nonfood use determination for an existing use, possible use cancellations, and an agreement on most mitigation proposals for worker exposure. (Danette Drew, 703-305-6028)

**Meeting with Aldicarb Registrant.** On November 10th, HED's RAB V/VII aldicarb team, along with staff from RD, BEAD, and EFED, met with representatives from AgLogic and their consultants to discuss dietary risk estimates resulting from consideration of proposed new domestic uses on oranges and grapefruit. The focus of the discussion was on the level of refinement used in current assessments. Clarification was provided concerning the basis for

the acute dietary point of departure, how food residue estimates were included from PDP monitoring results, and how percent crop treated estimates were determined from usage information. (Will Donovan, 703-305-7330)

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**Meetings with Crop Life America's Human Health Toxicology and Exposure Groups.** Two meetings were held with staff from OPP (HED and IO) and representatives from Crop Life America's human health toxicology and exposure groups. As requested by Crop Life America, OPP provided an update on a wide range of topics, including:

- new approach methodologies;
- reevaluation of HPPD inhibiting chemicals;
- dermal triple pack retrospective;
- cumulative screening;
- dietary refinements;
- the import tolerance pilot project; and
- the recent reorganization of OCSPP.

Given there is often overlap in topics, OPP requested that Crop Life America coordinate with their groups to schedule one meeting in the future to allow for consistent communication to all representatives at once. (Monique Perron, 703-347-0395)

**American Chemistry Council (ACC) Meeting on Threshold of Toxicological Concern (TTC).** On November 12th, OPP, OPPT and ORD staff participated in a kick-off meeting hosted by the ACC to develop a manuscript that explores opportunities for incorporating TTC in TSCA assessment. Participants from EPA, ACC, industry, and NGOs discussed possible journals for submission and timing for article submission, terms of reference, and paper outlines including topics such as TTC approaches for new and existing chemicals, route-specific and internal TTC, exposure assessment and other areas to consider. The first draft is planned to be completed in December 2020. (Cecilia Tan, 919-541-2542)

**HED Participates in AHPA Meeting with IO.** The American Herbal Products Association (AHPA) requested a meeting with the OPP IO to discuss the recently published Crop Group 25: Herb Group and Crop Group 26: Spice Group, that revised and considerably expand the previous Crop Group 19: Herbs and Spices Group. In addition to HED managers and scientists, RD and OGC were also in attendance. The majority of the discussion centered on the possibility of establishing default tolerance values for herbs and spices to account for inadvertent residues, similar to what are used by the PMRA and the EU, which would encourage international harmonization of commodity tolerances. OGC provided preliminary thoughts on the legal requirements and HED discussed potential data requirements. HED and RD will meet internally to consider the criteria used by international partners for setting default

tolerances and review relevant GAO reports regarding violative pesticide residues in herbal supplements. A later follow-on meeting is planned to discuss AHPA's thoughts and questions on Crop Group 25/26. (Philip Villanueva, 703-308-8665)

**Health and Environmental Science Institute (HESI) Environmental Epidemiology Work Group Meeting.** David Miller attended (as one of three co-chairs of the HESI Environmental Epidemiology Workgroup) a webinar with the Michael J. Fox Foundation organized by HESI. This is part of an effort by the HESI Environmental Epidemiology Workgroup to organize a focus group comprised of funders of epidemiology studies. The purpose of the focus group is to explore and help better understand how studies are funded with the idea of identifying paths forward to increase the use of epidemiology in quantitative human health risk assessment and potentially identify and remove barriers or limitations to such increased use. The presentation was given by HESI staff and began with background on HESI and the HESI Workgroup's activities in this area. HESI then described a series of three fictional study proposals to a fictional foundation that were designed to better bring out for future discussion issues and considerations regarding study design and utility as well as data openness and transparency. (David Miller, 703 305 5352)

**HED Briefing to OPP IO on International Projects.** HED Staff provided a briefing to OPP's Office Director, Ed Messina, on international activities led by HED. The international presentation covered a range of topics in food safety and risk assessment and included an overview of the Codex Committee on Pesticide Residues, the Joint FAO/WHO Meeting on Pesticide Residues, the Pesticide Program of the Organisation for Economic Co-operation and Development, and the UN Rotterdam and Stockholm Conventions. (Aaron Niman, 703-347-8184)

| Chemical | Deliverable | Branch |
|---|---|---|
| Dinotefuran | Section 3 Human Health Risk Assessment | RAB VI |
| Broflanilide | Section 18 Human Health Risk Assessment | RAB VI |

For HED

**Ex. 5 Deliberative Process (DP)**

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